

Title of Project: A Mobile App to Enhance Smoking Cessation Shared Decision Making
in Primary Care

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Structured Abstract

Purpose: Primary care physicians (PCPs) have a unique opportunity to help patients quit smoking, but they need tools to quickly and effectively engage patients and share with them the best evidence-based treatments. This project's goals were to develop and test such a tool by way of a tablet-based app for use in the doctor's office.

Scope: With so many options for cessation support, it is important for clinicians to personalize evidence-based interventions that are both useful and appealing to patients. During primary care office visits with competing priorities, applying patient-centered outcomes research (PCOR) for any given problem can be challenging. To address these opportunities and challenges, we developed and tested a tablet-based mHealth application (e-Quit worRx) to assist PCPs in disseminating PCOR evidence to support shared decision making about smoking cessation.

Methods: Within an academic health center and associated primary care network (3 practices) we designed, built, refined, and usability tested a novel iPad-based decision support app for smoking cessation. We then conducted a controlled single-crossover pilot trial to determine acceptability in practice.

Results: We successfully designed a usable interactive iPad-based decision aid. Our app engaged patients and physicians in smoking cessation conversations and significantly increased time spent discussing smoking cessation with their PCP and the likelihood that a decision was made at the time of the visit. Strong positive trends were observed in other study measures as well.

Key Words: smoking cessation, shared decision-making, decision aid, iPad, pragmatic, patient-centered outcomes research, mHealth

PURPOSE

Smoking is the leading preventable cause of death in the United States. Primary care physicians have a unique opportunity to help patients quit smoking, but they need tools to quickly and effectively engage patients and share with them the best evidence-based treatments. This project's goals were to develop and test such a tool by way of a tablet-based app for use in the doctor's office.

Objectives: In Aim 1 we aimed to develop an acceptable and usable smoking cessation decision aid that incorporated PCOR evidence into an mHealth tablet-based application called e-Quit worRx. The primary outcome was usability. In Aim 2 we pilot tested the final e-Quit worRx app compared to a generic pamphlet in primary care offices, with a goal of enhancing patient-centered shared decision-making about smoking cessation. The primary outcomes of Aim 2 were app feasibility in primary care and enhanced patient-centered shared decision-making.

SCOPE

Background. Smoking is the leading preventable cause of morbidity and mortality in the United States. Although numerous interventions improve the likelihood of successful smoking cessation and the resulting health benefits, most smokers relapse or require several intervention attempts before staying quit. Primary care physicians (PCPs) have a unique opportunity to discuss smoking cessation evidence in a way that enhances patient-initiated change.

With so many options for cessation support, it is important for clinicians to personalize evidence-based interventions that are both useful and appealing to patients.

During primary care office visits with competing priorities, applying patient-centered outcomes research (PCOR) for any given problem can be challenging. To address these opportunities and challenges, we developed and tested a tablet-based mHealth application (e-Quit worRx) to assist PCPs in disseminating PCOR evidence to support shared decision making about smoking cessation.

Context/Setting.

Aim 1: App Development. Our research team included content experts in primary care (Tubb and Elder), qualitative and practice-based research (Elder and Regan), smoking cessation and social work (Acquavita), sociology and geriatric medicine (Regan), health technology (Doarn and Harnett), nursing (Vonder Meulen), and data analysis (Pallerla). Team members met regularly and carried out Aim 1 app development in an academic health center setting.

We collected and integrated feedback from multiple sources throughout the design process. Stakeholders were recruited for interviews and focus groups using the snowball technique to provide feedback during various points in app development. Stakeholders included patients, physicians/providers, medical support staff, and smoking cessation research and clinical experts. Total included stakeholders consisted of 10 patients, 7 clinical support staff members (MAs, RNs), 8 PCPs (MDs, APNs), and 9 smoking cessation experts.

Aim 2: Pilot Study. We carried out the Aim 2 pilot study within the UC Health Primary Care Network at 3 different primary care offices. 52 PCPs and 35 support staff consented to participate among the 3 sites. Goal recruitment was 72, 12 control and 12

intervention patients from each of the 3 sites. Patient recruitment for app development and the pilot trial used similar methods and eligibility criteria, described in methods below.

METHODS

Study Design.

App Design Process. App design (Figure 1) began with a simple storyboard prepared for the grant application. We then integrated information from a thorough literature review including the Smoking Cessation Guidelines for Clinicians and Cochrane reviews as well as other published PCOR studies in the areas of primary care, smoking cessation medications, mHealth tools, and decision aids. Concurrently we began the stakeholder focus groups and interviews.

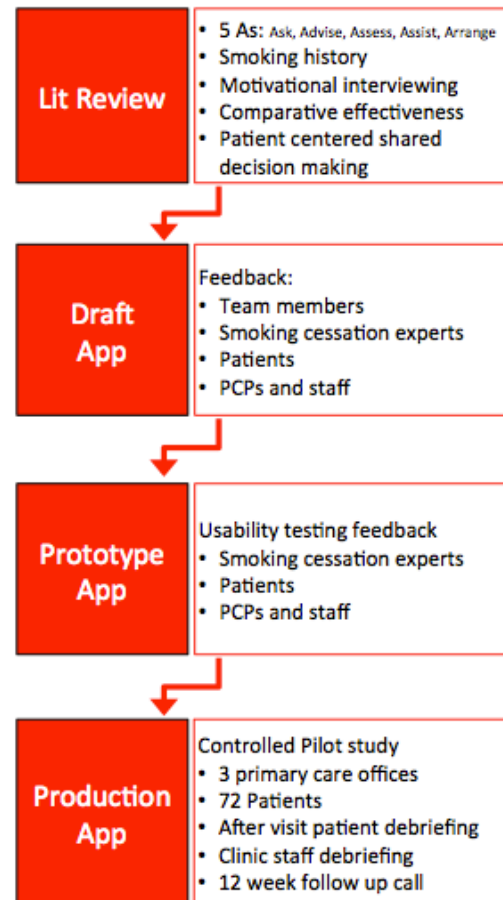


Figure 1: Study Flow and App Design Process

e-Quit worRx Coding and Design. We worked with master level students in computer science to code and build the app itself, both its behind-the-scenes engine and the front-facing user interface. Code for the app was written in Apple's Xcode software on a MacMini using the iOS-specific Swift programming language. Code versions were archived in Github. Prototype apps were tested on 3 iPad2 devices. The graphical user interface (GUI) is unidirectional but uses branching logic based on user input. The app

begins with a splash screen followed by a secure login screen so that user data are encrypted on the device. User input, including audio capture from the exit interview, is temporarily stored on the device in an app-based database until the session is complete. The RA then uploads the data wirelessly through an API to a HIPPA-compliant REDCap database whose redundant servers are housed at Cincinnati Children's Hospital Medical Center.

Iterative Usability Testing with Stakeholders and End-Users. Once a prototype app (version 1.0) was complete, a second round of key informant interviews was completed with patients, clinicians, and clinical support staff. These interviews focused on usability and included a modified system usability scale as well as a semi-structured questionnaire. Interviews touched upon participants' experiences using the app, recommendations for modifications, and evaluations of specific app components. Initial rounds of testing used concurrent think aloud techniques to elicit real time feedback and emotional responses. Later rounds of testing used retrospective think aloud techniques to assess important metrics such as accuracy and time needed to complete tasks on the app. At least 4 app versions were tested with users, with changes between versions ranging from relatively minor content revisions or additions to major changes to the GUI. After iterative usability testing, a final app version was ready for pilot testing in the clinical setting.

Health IT and clinical integration. Full integration with the electronic medical record was not in the scope of this project. However, the project did require a fair amount of work to integrate into the clinical environment. Tasks included network access for the study iPads, printing functionality, HIPPA-compliant email functionality, development of

parallel EMR-tools to assist clinicians including development of a new SmartSet order set for smoking cessation and SmartPhrases to quickly document key study data, and finally troubleshooting once the pilot study began.

Pilot Trial. A single crossover controlled cohort design was used for the pragmatic pilot trial. At each of the 3 sites we first recruited and enrolled all of the control patients, then trained staff and providers on the use of the app, then recruited and enrolled all of the intervention patients. The trial consisted of a single study visit and a 12-week follow up phone call. The study visit occurred at a previously scheduled visit with the patient's PCP. Our pragmatic design incorporated the decision aid app into current smokers' waiting time for their physician in the exam room, so the physician need only review their responses and personal selections to finalize treatment choices. After the visit, our research nurse completed an exit interview with all enrolled patients. After the study period at each site, our research team conducted a focus group with providers and another with medical support staff. Finally, we contacted all patients 12 weeks after their study visit for a short phone interview.

Data Sources/Collection and Measures.

A mixed methods approach was taken for both Aim 1 app design and Aim 2 pilot trial. Aim 1 data sources included qualitative feedback from semi-structured interviews and focus groups with key stakeholders, System Usability Scale (SUS) results, and feedback and discussions among our research team members. The **primary outcome** of Aim 1 was usability.

For Aim 2, we focused on several patient-centered and smoking-relevant

outcomes. Data sources included demographics and smoking history data collected by the app, an exit interview with the patient, 12-week follow-up telephone call, and semi-structured focus groups with PCPs and staff. Post-study focus groups at all site combined included 16 providers and 40 office staff. Focus groups transcribed and analyzed using editing method. Patient-centered outcomes were shared decision-making, decisional conflict, and quality of patient-physician communication. Secondary outcomes included app usability and acceptability by patient and the primary care practice and smoking-relevant outcomes including stage of change progression and self-reported smoking cessation rates after 12 weeks. Specific measures and scales included stage of change at the study visit and 12-week phone calls, the SDM-Q-9 shared decision-making score, SURE score for decisional conflict, select usability and acceptability questions from the exit interview, and 12 week quit rates. The **primary outcomes** of the pilot trial were app feasibility in primary care and enhanced patient centered shared decision-making.

Intervention.

The intervention in this study involved asking the patient to use the e-Quit worRx iPad app while waiting in the exam room for their PCP. Briefly, the app gathered a comprehensive smoking history, stage of change, dependence level then presents patients with customized personalized feedback and evidence-based strategies to quit; and finally provided a summary to the PCP as a platform for shared decision-making. Intervention patients also had the option to have a summary of their results printed or emailed to them and their PCP could print a summary for scanning into the EMR.

This intervention was contrasted to the control group who were asked to review a governmental smoking cessation booklet during their wait. The booklet was a standard 9-page smoking cessation booklet, “Help for Smokers and Other Tobacco Users,” from the U.S. Department of Health and Human Services, which had been used in other similar studies.

RESULTS

Principal Findings/Outcomes.

App Refinement and Usability Testing. Stakeholder feedback was obtained iteratively prior to the first app version and with each of 5 app versions. Based on feedback revisions in app content, appearance, and flow were made. Testing of version 2.2 produced feedback that the literacy level was too high for the clinic populations we serve. A literacy evaluation revealed that our initial text averaged a 7th grade reading level. Between app versions 2.2 and 2.3 we made text edits screen-by-screen focusing on improving readability and we reduced the average to a 5th grade reading level (Figure 2).

Usability as assessed with the System Usability Score (SUS)

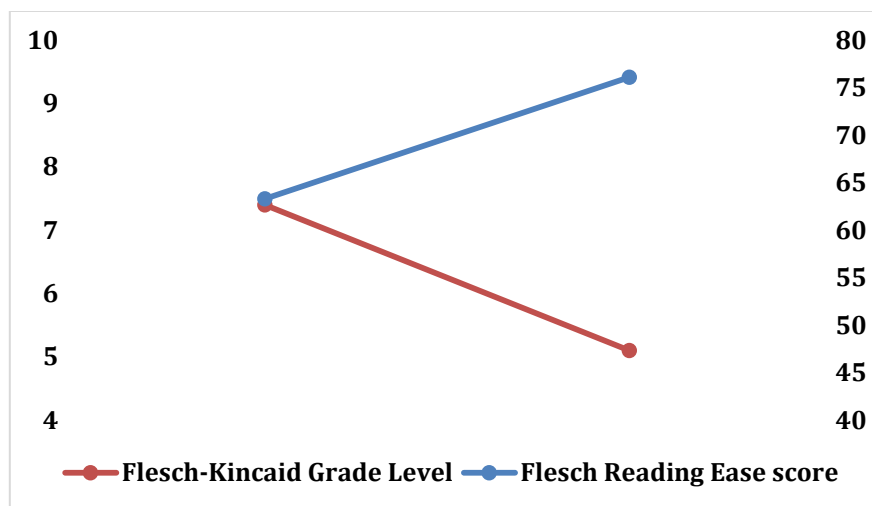


Figure 2: Grade level (left scale) and Reading Ease score (right scale) for app version 2.2 (left) and 2.3 (right)

increased with each version for a final of 90/100, above 65 considered “usable” (Figure 3).

Description of e-Quit worRx. Figure 4

includes screenshots of a demographics screen from concept to final app. Key components of the app are reasons for and against smoking, treatment options including their level of evidence, risks, and costs.

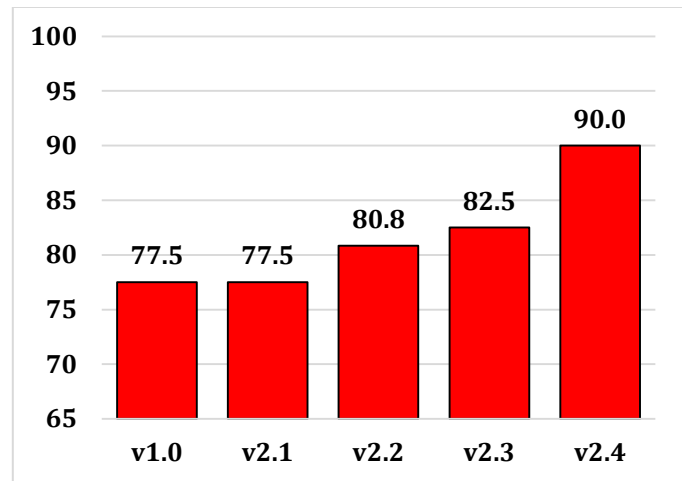


Figure 3 SUS score across app versions

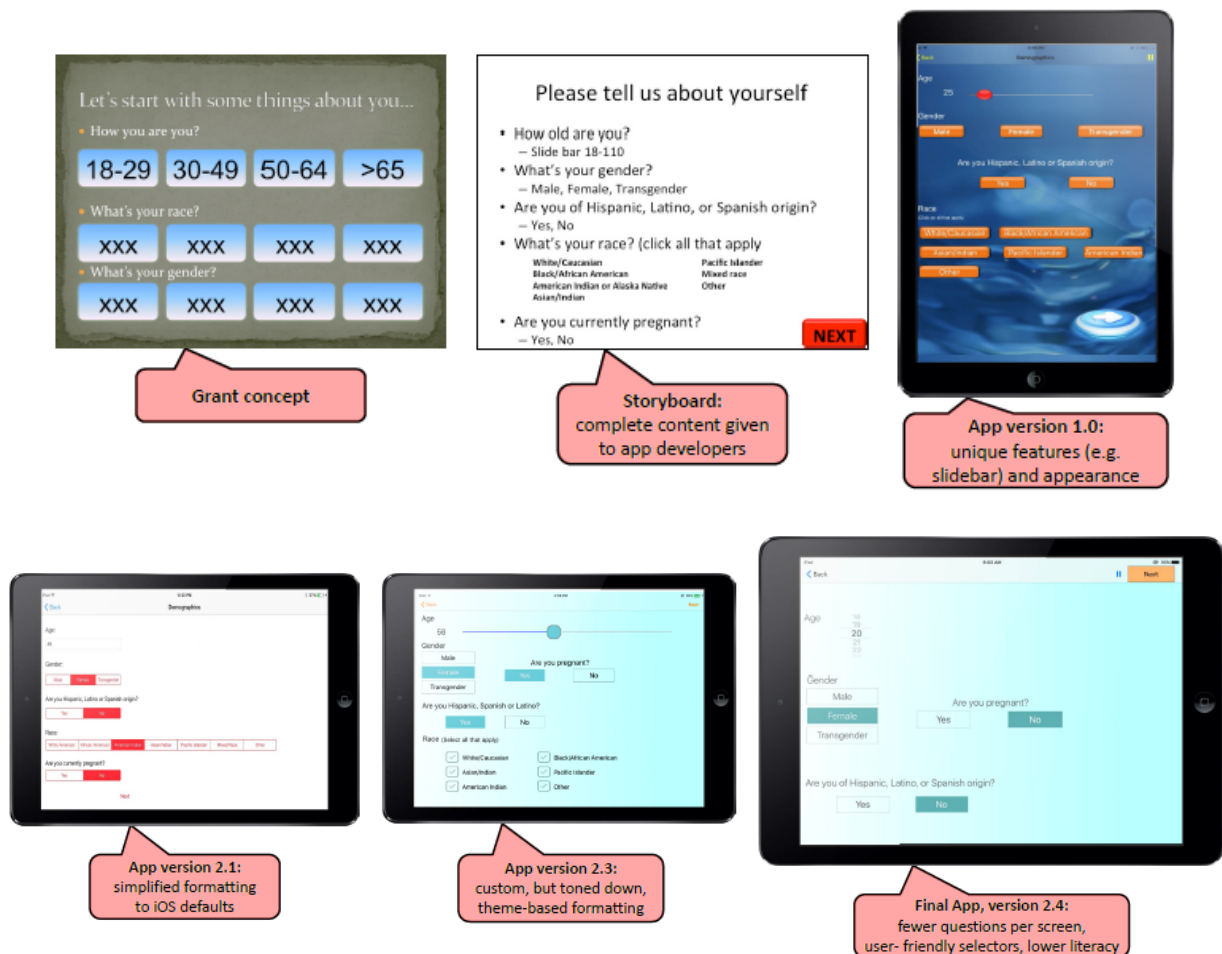


Figure 4: Development of a single e-Quit worRx screenshot from Grant Concept, to Storyboard, through iterative App versions

Treatment options include medications, therapy, alternative therapies and other

treatments such as quit lines and mHealth tools. The app was designed to personalize

users' examination of the positive and negative effects of smoking and increase their knowledge of smoking cessation treatment options. In addition to summarizing their personal considerations about the pros and cons of smoking, based on participants' prior input it summarizes interest in the various cessation aids including information on their comparative effectiveness, costs (compared to current smoking costs), and risks. Patients can then select their preferred treatment. Again based upon an individual's input, a summary screen is saved to facilitate discussion with their physician that includes personalized information derived from their responses. The app includes a provider input screen where a plan is selected and an exit interview to be completed by the research team after the clinical encounter.

Pilot Trial. 73 patients were enrolled and completed the study visit, 36 control patients and 37 intervention patients. Study visits included 22 of the enrolled PCPs.

App Collected Data. Demographics of control and intervention groups were similar with no significant differences. 50% were white, 46% black, and 4% other. 64% were female. Education level ranged from less than high school to professional degree, but 73% made less than \$50,000 per year and insurance payer varied widely. 38% lived with another smoker. 33% of control patients and 31% of intervention patients were in the preparation stage of change at the time of the study visit ($p=0.83$). For 12 of the 37 intervention patients (32%), providers endorsed that using the app changed their smoking cessation plan at the visit but providers stated that in 35 of 37 cases (95%) the app promoted shared decision-making.

Exit Interview Data.

There was no difference in endorsing “learned new ways to quit smoking (56 vs. 57%) but there was a trend toward

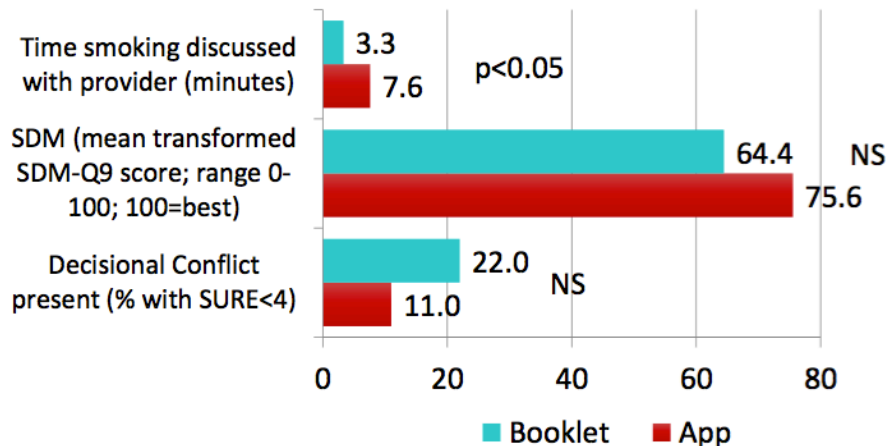


Figure 5: Select Exit Interview Data

more intervention patients endorsing that they “learned about smoking and addiction” than control patients (42% intervention vs. 26% control, $p=0.20$). Patient-reported time spent by their doctor discussing smoking cessation was significantly higher for intervention patients (7.6 min vs. 3.3 min; $p < 0.05$) (Figure 5) and there was a trend for intervention patients more than controls for endorsing that “the app/booklet affected their conversation with their provider” (57% vs. 34% control, $p=0.08$). More intervention patients stated that a decision was made about their smoking, even if the decision was to make no changes (97% vs. 67%, $p=0.001$) and there was a trend toward less decisional conflict (11% vs. 22%) among intervention patients than control patients ($p=0.21$) and a trend toward improved patient-reported shared decision-making (primary outcome) for intervention vs. control (average SDM score 76/100 intervention, 64/100 control, $p=0.16$). 95% of intervention patients said they would want to use an app like this at their doctor’s office in the future outside of a paid study.

Qualitative data from exit interviews and focus groups. Themes developed from analysis of patient exit interviews and provider and staff focus groups are shown in the Table.

12 week follow up data. 83% of the 73 enrolled subjects completed their 12-week follow up phone calls. Few differences were apparent between control and intervention groups. Among all enrolled patients, 88% were still smoking at the

Providers felt app engaged patients	
"It initiated the husband and wife to set up quit smoking dates."	"It involves them in the process. They're more engaged & so are you."
Staff had workflow concerns	
"It needs to be less questions and easier. Our patient literacy level is low; we have no time to help them through."	"It gets the patients attention and you want to catch them when they're present...it would help to be on the internet to fill out beforehand."
Patients found it easy to use	
"It was very easy, just do what it says and answer the questions; [it was] basic, user-friendly."	"Easy enough where I could read it with a 3 rd grade reading level."

Table: Qualitative Feedback on App from Patient Exit Interviews and PCP and Staff Focus Groups

time of their follow-up phone call, though 79% had quit for at least 24 hours within the last year and 64% made a quit attempt since their study visit including 25% who used a cessation aid. 35% of patients had seen their PCP to discuss smoking cessation since the study visit. No differences were found between the control booklet and intervention app in questions about being helpful in choosing a cessation aid, motivation to quit or confidence in cessation success with next attempt.

At the time of the follow-up calls, 22% of control patients but 46% of intervention patients endorsed that they were seriously thinking of quitting smoking within the next 30 days (preparation) ($p=0.11$). Considering that at the study visit about 32% of both

groups were in preparation stage, this represented a strong trend toward a larger proportion of intervention patients than control patients had progressed to preparation stage ($p=0.052$)

Limitations.

Our study had a few predicted and unforeseen limitations. We were not, as we had foreseen, able to fully integrate the app into the EHR so that patient selections and chosen interventions would populate into the medical record. After discussing with our health IT department, both our timeframe and budget were far too small for this.

We were able to integrate into the clinic sites in several ways. We gained access to the network and internet connection, allowing real time secure data transfer to our database, we enabled automated email messaging to patients at the end of the session summarizing interventions chosen, and we build new matching templates (i.e. SmartPhrases and a SmartSet order set) for our EHR so that providers could quickly copy over patient selections from the study. Finally, though the existing clinic printers could not be used to print from our app, we placed AirPrint enabled printers at each site to allow printing summaries for patients and PCPs.

Another limitation was that we were unable to create a generic enough application framework so that clinical content could be swapped out to create decision aid apps for other clinical scenarios, diabetes medicine selection for example. This is an initial goal, but during the app design process we made a decision to choose personalization for the patient over future generalizability.

We also were surprised to find that not only would much more work have to go into making our iPad app compatible with iPhones or even Android devices, but we had to pick landscape or portrait display on the iPad instead of allowing the user to decide to ensure the app displayed correctly on the screen. Making the display orientation neutral would have required more programming time than our study allowed for.

As a pilot trial our small sample size leave open the possibility that many of the result trends may have reached significance in a larger study. The biggest unforeseen limitation was that some study data was lost and couldn't be analyzed due to a database error that we didn't notice until data collection was completed. For example nearly all cigarette quantity data were lost meaning we couldn't calculate Fagerstrom dependence levels. The loss of these few data points did not significantly impede our analysis and did not affect the study visit at all since the data was displayed for the patient and provider, being lost in the data transfer to the REDCap database.

Discussion/Conclusions.

Through this project we successfully created a usable and acceptable iPad app-based decision aid for use in primary care offices. The design process presented several challenges including navigating requests to our coders for repeated changes to both content and design, resolving conflicting feedback from our diverse group of stakeholders and even within our study group, realizing the time-intensity of editing content and code, and integration into a clinical setting.

We successfully ran a pragmatic pilot trial in 3 primary care offices using a technology novel to many of the users. Our app engaged patients and physicians in

smoking cessation conversations and significantly increased time spent discussing smoking cessation with their PCP and the likelihood that a decision was made at the time of the visit. For the primary outcome, shared decision-making, PCPs strongly endorsed that the app promoted SDM and a positive trend was observed for patient-reported SDM. Positive trends were also observed in other measures including decreased decisional conflict and especially for intervention patients progressing into preparation stage of change at the time of their 12-week follow up.

Overall, the app was easy to use but office flow concerns were raised. One possible solution to this would be integration with the patient portal so patient could complete the app prior to their visit.

Significance/Implications.

To our knowledge this is the first iPad app-based decision aid for smoking cessation that was designed using evidence-based methods to be used in a clinical setting. If this technology can be further integrated into EHR systems we think acceptability to providers will increase and apps like these have the potential to improve patient-centered care, shared decision-making and patient engagement and empowerment.

LIST OF PUBLICATIONS AND PRODUCTS

- Invention statement: see submitted “Confidential Software Form” for the iOS application “e-Quit worRx”
- 2 manuscripts are in preparation covering Aim 1 and Aim 2 activities.
Submission planned Spring 2018 and Summer 2018, respectively